AMENDMENT IN THE NATURE OF A SUBSTITUTE TO H.R. 4157

OFFERED BY MR. DEAL

(including an amendment to the title)

Strike all after the enacting clause and insert the following:

1 SEC. 1. SHORT TITLE AND TABLE OF CONTENTS.

- 2 (a) Short Title.—This Act may be cited as the
- 3 "Better Health Information System Act of 2006".
- 4 (b) Table of Contents of table of contents of
- 5 this Act is as follows:
 - Sec. 1. Short title and table of contents.
 - Sec. 2. Preserving privacy and security laws.

TITLE I—COORDINATION FOR, PLANNING FOR, AND INTEROPERABILITY OF HEALTH INFORMATION TECHNOLOGY

- Sec. 101. Office of the National Coordinator for Health Information Technology.
- Sec. 102. Report on the American Health Information Community.
- Sec. 103. Interoperability planning process; Federal information collection activities
- Sec. 104. Ensuring health care providers may maintain health information in electronic form.
- Sec. 105. Study and report on State, regional, and community health information exchanges.

TITLE II—EXPEDITED MODIFICATION PROCEDURES FOR AND ADOPTION OF TRANSACTIONAL STANDARDS AND CODES

- Sec. 201. Procedures to ensure timely updating of standards that enable electronic exchanges.
- Sec. 202. Upgrading ASC X12 and NCPDP standards.

TITLE III—PROMOTING THE USE OF HEALTH INFORMATION TECHNOLOGY TO BETTER COORDINATE HEALTH CARE

- Sec. 301. Safe harbors to antikickback civil penalties and criminal penalties for provision of health information technology and training services
- Sec. 302. Exception to limitation on certain physician referrals (under Stark) for provision of health information technology and training services to health care professionals.

1 SEC. 2. PRESERVING PRIVACY AND SECURITY LAWS.

- 2 Nothing in this Act (or the amendments made by this
- 3 Act) shall be construed to affect the scope, substance, or
- 4 applicability of section 264(c) of the Health Insurance
- 5 Portability and Accountability Act of 1996 and any regu-
- 6 lation issued pursuant to such section.

7 TITLE I—COORDINATION FOR,

- 8 PLANNING FOR, AND INTER-
- 9 **OPERABILITY OF HEALTH IN-**
- 10 FORMATION TECHNOLOGY
- 11 SEC. 101. OFFICE OF THE NATIONAL COORDINATOR FOR
- 12 HEALTH INFORMATION TECHNOLOGY.
- (a) IN GENERAL.—Title II of the Public Health Serv-
- 14 ice Act is amended by adding at the end the following new
- 15 part:
- 16 "Part D—Health Information Technology
- 17 "OFFICE OF THE NATIONAL COORDINATOR FOR HEALTH
- 18 INFORMATION TECHNOLOGY
- 19 "Sec. 271. (a) Establishment.—There is estab-
- 20 lished within the Department of Health and Human Serv-
- 21 ices an Office of the National Coordinator for Health In-
- 22 formation Technology that shall be headed by the National

1	Coordinator for Health Information Technology (referred
2	to in this part as the 'National Coordinator'). The Na-
3	tional Coordinator shall be appointed by and report di-
4	rectly to the Secretary. The National Coordinator shall be
5	paid at a rate equal to the rate of basic pay for level IV
6	of the Executive Schedule.
7	"(b) Goals of Nationwide Interoperable
8	HEALTH INFORMATION TECHNOLOGY INFRASTRUC-
9	TURE.—The National Coordinator shall perform the du-
10	ties under subsection (c) in a manner consistent with the
11	development of a nationwide interoperable health informa-
12	tion technology infrastructure that—
13	"(1) improves health care quality, promotes
14	data accuracy, reduces medical errors, increases the
15	efficiency of care, and advances the delivery of ap-
16	propriate, evidence-based health care services;
17	"(2) promotes wellness, disease prevention, and
18	management of chronic illnesses by increasing the
19	availability and transparency of information related
20	to the health care needs of an individual for such in-
21	dividual;
22	"(3) promotes the availability of appropriate
23	and accurate information necessary to make medical
24	decisions in a usable form at the time and in the lo-
25	cation that the medical service involved is provided;

1	"(4) produces greater value for health care ex-
2	penditures by reducing health care costs that result
3	from inefficiency, medical errors, inappropriate care,
4	and incomplete or inaccurate information;
5	"(5) promotes a more effective marketplace,
6	greater competition, greater systems analysis, in-
7	creased consumer choice, enhanced quality, and im-
8	proved outcomes in health care services;
9	"(6) with respect to health information of con-
10	sumers, advances the portability of such information
11	and the ability of such consumers to share and use
12	such information to assist in the management of
13	their health care;
14	"(7) improves the coordination of information
15	and the provision of such services through an effec-
16	tive infrastructure for the secure and authorized ex-
17	change and use of health care information;
18	"(8) is consistent with legally applicable re-
19	quirements with respect to securing and protecting
20	the confidentiality of individually identifiable health
21	information of a patient;
22	"(9) promotes the creation and maintenance of
23	transportable, secure, Internet-based personal health
24	records, including promoting the efforts of health
25	care payers and health plan administrators for a

1	health plan, such as Federal agencies, private health
2	plans, and third party administrators, to provide for
3	such records on behalf of members of such a plan;
4	"(10) promotes access to and review of the elec-
5	tronic health record of a patient by such patient;
6	"(11) promotes health research and health care
7	quality research and assessment; and
8	"(12) promotes the efficient and streamlined
9	development, submission, and maintenance of elec-
10	tronic health care clinical trial data.
11	"(c) Duties of the National Coordinator.—
12	"(1) Strategic planner for interoper-
13	ABLE HEALTH INFORMATION TECHNOLOGY.—The
14	National Coordinator shall provide for a strategic
15	plan for the nationwide implementation of interoper-
16	able health information technology in both the public
17	and private health care sectors consistent with sub-
18	section (b).
19	"(2) Principal advisor to the sec-
20	RETARY.—The National Coordinator shall serve as
21	the principal advisor to the Secretary on the develop-
22	ment, application, and use of health information
23	technology, and shall coordinate the policies and pro-
24	grams of the Department of Health and Human

1	Services for promoting the use of health information
2	technology.
3	"(3) Intragovernmental coordinator.—
4	The National Coordinator shall ensure that health
5	information technology policies and programs of the
6	Department of Health and Human Services are co-
7	ordinated with those of relevant executive branch
8	agencies and departments with a goal to avoid dupli-
9	cation of effort, to align the health information ar-
10	chitecture of each agency or department toward a
11	common approach, and to ensure that each agency
12	or department conducts programs within the areas
13	of its greatest expertise and its mission in order to
14	create a national interoperable health information
15	system capable of meeting national public health
16	needs effectively and efficiently. The coordination
17	authority provided to the National Coordinator
18	under the previous sentence shall supercede any
19	such authority otherwise provided to any other Fed-
20	eral official.
21	"(4) Advisor to omb.—The National Coordi-
22	nator shall provide to the Director of the Office of
23	Management and Budget comments and advice with
24	respect to specific Federal health information tech-
25	nology programs.".

(b) Treatment of Executive Order 13335.—Ex-

2	ecutive Order 13335 shall not have any force or effect
3	after the date of the enactment of this Act.
4	(c) Transition From ONCHIT Under Executive
5	Order.—
6	(1) In general.—All functions, personnel, as-
7	sets, liabilities, administrative actions, and statutory
8	reporting requirements applicable to the old Na-
9	tional Coordinator or the Office of the old National
10	Coordinator on the date before the date of the enact-
11	ment of this Act shall be transferred, and applied in
12	the same manner and under the same terms and
13	conditions, to the new National Coordinator and the
14	Office of the new National Coordinator as of the
15	date of the enactment of this Act.
16	(2) Rule of Construction.— Nothing in this
17	section or the amendment made by this section shall
18	be construed as requiring the duplication of Federal
19	efforts with respect to the establishment of the Of-
20	fice of the National Coordinator for Health Informa-
21	tion Technology, regardless of whether such efforts
22	are carried out before or after the date of the enact-
23	ment of this Act.
24	(3) ACTING NATIONAL COORDINATOR.—Before
25	the appointment of the new National Coordinator,

1	the old National Coordinator shall act as the Na-
2	tional Coordinator for Health Information Tech-
3	nology until the office is filled as provided in section
4	271(a) of the Public Health Service Act, as added
5	by subsection (a). The Secretary of Health and
6	Human Services may appoint the old National Coor-
7	dinator as the new National Coordinator.
8	(4) Definitions.—For purposes of this sub-
9	section:
10	(A) NEW NATIONAL COORDINATOR.—The
11	term "new National Coordinator" means the
12	National Coordinator for Health Information
13	Technology appointed under section 271(a) of
14	the Public Health Service Act, as added by sub-
15	section (a).
16	(B) OLD NATIONAL COORDINATOR.—The
17	term "old National Coordinator" means the
18	National Coordinator for Health Information
19	Technology appointed under Executive Order
20	13335.
21	SEC. 102. REPORT ON THE AMERICAN HEALTH INFORMA-
22	TION COMMUNITY.
23	Not later than one year after the date of the enact-
24	ment of this Act, the Secretary of Health and Human
25	Services shall submit to Congress a report on the work

1	conducted by the American Health Information Commu-
2	nity (in this section referred to as "AHIC"), as established
3	by the Secretary. Such report shall include the following:
4	(1) A description of the accomplishments of
5	AHIC, with respect to the promotion of the develop-
6	ment of national guidelines, the development of a
7	nationwide health information network, and the in-
8	creased adoption of health information technology.
9	(2) Information on how model privacy and secu-
10	rity policies may be used to protect confidentiality of
11	health information, and an assessment of how exist-
12	ing policies compare to such model policies.
13	(3) Information on the progress in—
14	(A) establishing uniform industry-wide
15	health information technology standards;
16	(B) achieving an internet-based nationwide
17	health information network; and
18	(C) achieving interoperable electronic
19	health record adoption across health care pro-
20	viders.
21	(4) Recommendations for the transition of
22	AHIC to a longer-term advisory and facilitation enti-
23	ty, including—
24	(A) a schedule for such transition;

1	(B) options for structuring the entity as ei-
2	ther a public-private or private sector entity;
3	(C) the role of the Federal Government in
4	the entity;
5	(D) steps for—
6	(i) continued leadership in the facilita-
7	tion of guidelines or standards;
8	(ii) the alignment of financial incen-
9	tives; and
10	(iii) the long-term plan for health care
11	transformation through information tech-
12	nology; and
13	(E) the elimination or revision of the func-
14	tions of AHIC during the development of the
15	nationwide health information network.
16	SEC. 103. INTEROPERABILITY PLANNING PROCESS; FED-
17	ERAL INFORMATION COLLECTION ACTIVI-
18	TIES.
19	Part D of title II of the Public Health Service Act,
20	as added by section 101, is amended by adding at the end
21	the following new section:
22	"INTEROPERABILITY PLANNING PROCESS; FEDERAL
23	INFORMATION COLLECTION ACTIVITIES
24	"Sec. 272. (a) Strategic Interoperability
25	PLANNING PROCESS —

1	"(1) Assessment and endorsement of
2	CORE STRATEGIC GUIDELINES.—
3	"(A) In General.—Not later than De-
4	cember 31, 2006, the National Coordinator
5	shall publish a strategic plan, including a sched-
6	ule, for the assessment and the endorsement of
7	core interoperability guidelines for significant
8	use cases consistent with this subsection. The
9	National Coordinator may update such plan
10	from time to time.
11	"(B) Consultation with other par-
12	TIES.—The National Coordinator shall develop
13	and implement such strategic plan in consulta-
14	tion with the American Health Information
15	Community and other appropriate entities.
16	"(C) Definitions.—For purposes of this
17	section:
18	"(i) Interoperability guide-
19	LINE.—The term 'interoperability guide-
20	line' means a guideline to improve and pro-
21	mote the interoperability of health infor-
22	mation technology for purposes of elec-
23	tronically accessing and exchanging health
24	information. Such term includes named
25	standards, architectures, software schemes

1	for identification, authentication, and secu-
2	rity, and other information needed to en-
3	sure the reproducible development of com-
4	mon solutions across disparate entities.
5	"(ii) Core interoperability guide-
6	LINE.—The term 'core interoperability
7	guideline' means an interoperability guide-
8	line that the National Coordinator deter-
9	mines is essential and necessary for pur-
10	poses described in clause (i).
11	"(iii) Significant use case.—The
12	term 'significant use case' means a cat-
13	egory (as specified by the National Coordi-
14	nator) that identifies a significant use or
15	purpose for the interoperability of health
16	information technology, such as for the ex-
17	change of laboratory information, drug
18	prescribing, clinical research, and elec-
19	tronic health records.
20	"(2) National survey.—
21	"(A) IN GENERAL.—Not later than August
22	31, 2008, the National Coordinator shall con-
23	duct one or more surveys designed to measure
24	the capability of entities (including Federal
25	agencies, State and local government agencies,

1	and private sector entities) to exchange elec-
2	tronic health information by appropriate signifi-
3	cant use case. Such surveys shall identify the
4	extent to which the type of health information,
5	the use for such information, or any other ap-
6	propriate characterization of such information
7	may relate to the capability of such entities to
8	exchange health information in a manner that
9	is consistent with methods to improve the inter-
10	operability of health information and with core
11	interoperability guidelines.
12	"(B) Dissemination of survey re-
13	SULTS.—The National Coordinator shall dis-
14	seminate the results of such surveys in a man-
15	ner so as to—
16	"(i) inform the public on the capabili-
17	ties of entities to exchange electronic
18	health information;
19	"(ii) assist in establishing a more
20	interoperable information architecture; and
21	"(iii) identify the status of health in-
22	formation systems used in Federal agen-
23	cies and the status of such systems with
24	respect to interoperability guidelines.

1	"(3) Endorsement of core interoper-
2	ABILITY GUIDELINES FOR SIGNIFICANT USE
3	CASES.—As part of the strategic plan under para-
4	graph (1) and not later than August 31, 2009, the
5	National Coordinator shall endorse core interoper-
6	ability guidelines for significant use cases. Compli-
7	ance with such guidelines shall be voluntary, subject
8	to subsection $(b)(1)$.
9	"(b) Federal Health Information Collection
10	ACTIVITIES.—
11	"(1) Requirements.—With respect to a core
12	interoperability guideline endorsed under subsection
13	(a)(3) for a significant use case, the President shall
14	take measures to ensure that Federal activities in-
15	volving the broad collection and submission of health
16	information are consistent with such guideline within
17	three years after the date of such endorsement.
18	"(2) Promoting use of non-identifiable
19	HEALTH INFORMATION TO IMPROVE HEALTH RE-
20	SEARCH AND HEALTH CARE QUALITY.—Where fea-
21	sible, and consistent with applicable privacy or secu-
22	rity or other laws, the President, in consultation
23	with the Secretary, shall take measures to allow ac-
24	cess to useful categories of non-identifiable health
25	information in records maintained by the Federal

1	government, or maintained by entities under con-
2	tract with the Federal government, to advance
3	health care quality and health research where such
4	information is in a form that can be used in such
5	research. The President shall consult with appro-
6	priate Federal agencies, and solicit public comment
7	on appropriate categories of information, and appro-
8	priate measures to take. The President may consider
9	costs, administrative burden, and the potential for
10	improvements in health care quality in determining
11	such appropriate measures.
12	"(3) Annual review and report.—For each
13	year during the five-year period following the date of
14	the enactment of this section, the National Coordi-
15	nator shall review the operation of health informa-
16	tion collection by and submission to the Federal gov-
17	ernment and the purchases (and planned purchases)
18	of health information technology by the Federal gov-
19	ernment. For each such year and based on the re-
20	view for such year, the National Coordinator shall
21	submit to the President and Congress recommenda-
22	tions on methods to—
23	"(A) streamline (and eliminate redundancy
24	in) Federal systems used for the collection and
25	submission of health information;

1	"(B) improve efficiency in such collection
2	and submission;
3	"(C) increase the ability to assess health
4	care quality; and
5	"(D) reduce health care costs.".
6	SEC. 104. ENSURING HEALTH CARE PROVIDERS MAY MAIN-
7	TAIN HEALTH INFORMATION IN ELECTRONIC
8	FORM.
9	Part D of title II of the Public Health Service Act,
10	as added by section 101(a) and amended by section 103,
11	is amended by adding at the end the following new section:
12	"ENSURING HEALTH CARE PROVIDERS MAY MAINTAIN
13	HEALTH INFORMATION IN ELECTRONIC FORM
14	"Sec. 273. (a) In General.—Any health care pro-
15	vider that participates in a health care program that re-
16	ceives Federal funds shall be deemed as meeting any re-
17	quirement for the maintenance of data in paper form
18	under such program (whether or not for purposes of man-
19	agement, billing, reporting, reimbursement, or otherwise)
20	if the required data is maintained in an electronic form.
21	"(b) Relation to State Laws.—Beginning on the
22	date that is one year after the date of the enactment of
23	this section, subsection (a) shall supersede any contrary
24	provision of State law.
25	"(c) Construction.—Nothing in this section shall
26	be construed as—

1	"(1) requiring health care providers to maintain
2	or submit data in electronic form;
3	"(2) preventing a State from permitting health
4	care providers to maintain or submit data in paper
5	form; or
6	"(3) preventing a State from requiring health
7	care providers to maintain or submit data in elec-
8	tronic form.".
9	SEC. 105. STUDY AND REPORT ON STATE, REGIONAL, AND
10	COMMUNITY HEALTH INFORMATION EX-
11	CHANGES.
12	(a) Study.—The Secretary of Health and Human
13	Services shall conduct a study on issues related to the de-
14	velopment, operation, and implementation of State, re-
15	gional, and community health information exchanges.
16	Such study shall include the following, with respect to
17	such health information exchanges:
18	(1) Profiles detailing the current stages of such
19	health information exchanges with respect to the
20	progression of the development, operation, imple-
21	mentation, organization, and governance of such ex-
22	changes.
23	(2) The impact of such exchanges on healthcare
24	quality, safety, and efficiency, including—

1	(A) any impact on the coordination of
2	health information and services across
3	healthcare providers and other organizations
4	relevant to health care;
5	(B) any impact on the availability of health
6	information at the point-of-care to make timely
7	medical decisions;
8	(C) any benefits with respect to the pro-
9	motion of wellness, disease prevention, and
10	chronic disease management;
11	(D) any improvement with respect to pub-
12	lic health preparedness and response;
13	(E) any impact on the widespread adoption
14	of interoperable health information technology
15	including electronic health records;
16	(F) any contributions to achieving an
17	Internet-based national health information net-
18	work; and
19	(G) any contribution of health information
20	exchanges to consumer access and to con-
21	sumers' use of their health information.
22	(3) Best practice models for financing
23	incentivizing, and sustaining such health information
24	exchanges.

1	(4) Information identifying the common prin-
2	ciples, policies, tools, and standards used (or pro-
3	posed) in the public and private sectors to support
4	the development, operation, and implementation of
5	such health information exchanges.
6	(5) A description of any areas in which Federal
7	government leadership is needed to support growth
8	and sustainability of such health information ex-
9	changes.
10	(b) REPORT.—Not later than one year after the date
11	of enactment of this Act, the Secretary of Health and
12	Human Services shall submit to Congress a report on the
13	study described in subsection (a), including such rec-
14	ommendations as the Secretary determines appropriate to
15	facilitate the development, operation, and implementation
16	of health information exchanges.

1	TITLE II—EXPEDITED MODIFICA-
2	TION PROCEDURES FOR AND
3	ADOPTION OF TRANS-
4	ACTIONAL STANDARDS AND
5	CODES
6	SEC. 201. PROCEDURES TO ENSURE TIMELY UPDATING OF
7	STANDARDS THAT ENABLE ELECTRONIC EX-
8	CHANGES.
9	Section 1174(b) of the Social Security Act (42 U.S.C.
10	1320d-3(b)) is amended—
11	(1) in paragraph (1)—
12	(A) in the first sentence, by inserting "and
13	in accordance with paragraph (3)" before the
14	period; and
15	(B) by adding at the end the following new
16	sentence: "For purposes of this subsection and
17	section 1173(c)(2), the term 'modification' in-
18	cludes a new version or a version upgrade.";
19	and
20	(2) by adding at the end the following new
21	paragraph:
22	"(3) Expedited procedures for adoption
23	OF ADDITIONS AND MODIFICATIONS TO STAND-
24	ARDS.—

1	"(A) In general.—For purposes of para-
2	graph (1), the Secretary shall provide for an ex-
3	pedited upgrade program (in this paragraph re-
4	ferred to as the 'upgrade program'), in accord-
5	ance with this paragraph, to develop and ap-
6	prove additions and modifications to the stand-
7	ards adopted under section 1173(a) to improve
8	the quality of such standards or to extend the
9	functionality of such standards to meet evolving
10	requirements in health care.
11	"(B) Publication of notices.—Under
12	the upgrade program:
13	"(i) Voluntary notice of initi-
14	ATION OF PROCESS.—Not later than 30
15	days after the date the Secretary receives
16	a notice from a standard setting organiza-
17	tion that the organization is initiating a
18	process to develop an addition or modifica-
19	tion to a standard adopted under section
20	1173(a), the Secretary shall publish a no-
21	tice in the Federal Register that—
22	"(I) identifies the subject matter
23	of the addition or modification;

1	"(II) provides a description of
2	how persons may participate in the
3	development process; and
4	"(III) invites public participation
5	in such process.
6	"(ii) Voluntary notice of pre-
7	LIMINARY DRAFT OF ADDITIONS OR MODI-
8	FICATIONS TO STANDARDS.—Not later
9	than 30 days after the date of the date the
10	Secretary receives a notice from a standard
11	setting organization that the organization
12	has prepared a preliminary draft of an ad-
13	dition or modification to a standard adopt-
14	ed by section 1173(a), the Secretary shall
15	publish a notice in the Federal Register
16	that—
17	"(I) identifies the subject matter
18	of (and summarizes) the draft;
19	"(II) specifies the procedure for
20	obtaining documentation for the draft;
21	"(III) provides a description of
22	how persons may submit comments in
23	writing and at any public hearing or
24	meeting held by the organization on
25	the draft; and

1	"(IV) invites submission of such
2	comments and participation in such
3	hearing or meeting.
4	"(iii) Notice of proposed addition
5	OR MODIFICATION TO STANDARDS.—Not
6	later than 30 days after the date of the
7	date the Secretary receives a notice from a
8	standard setting organization that the or-
9	ganization has a proposed addition or
10	modification to a standard adopted under
11	section 1173(a) that the organization in-
12	tends to submit under subparagraph
13	(D)(iii), the Secretary shall publish a no-
14	tice in the Federal Register that contains,
15	with respect to the proposed addition or
16	modification, the information required in
17	the notice under clause (ii) with respect to
18	a preliminary draft of an addition or modi-
19	fication.
20	"(iv) Construction.—Nothing in
21	this paragraph shall be construed as re-
22	quiring a standard setting organization to
23	request the notices described in clauses (i)
24	and (ii) with respect to an addition or
25	modification to a standard in order to

1	qualify for an expedited determination
2	under subparagraph (C) with respect to a
3	proposal submitted to the Secretary for
4	adoption of such addition or modification.
5	"(C) Provision of expedited deter-
6	MINATION.—Under the upgrade program and
7	with respect to a proposal by a standard setting
8	organization for an addition or modification to
9	a standard adopted under section 1173(a), if
10	the Secretary determines that the standard set-
11	ting organization developed such addition or
12	modification in accordance with the require-
13	ments of subparagraph (D) and the National
14	Committee on Vital and Health Statistics rec-
15	ommends approval of such addition or modifica-
16	tion under subparagraph (E), the Secretary
17	shall provide for expedited treatment of such
18	proposal in accordance with subparagraph (F).
19	"(D) REQUIREMENTS.—The requirements
20	under this subparagraph with respect to a pro-
21	posed addition or modification to a standard by
22	a standard setting organization are the fol-
23	lowing:
24	"(i) Request for publication of
25	NOTICE.—The standard setting organiza-

1	tion submits to the Secretary a request for
2	publication in the Federal Register of a no-
3	tice described in subparagraph (B)(iii) for
4	the proposed addition or modification.
5	"(ii) Process for receipt and
6	CONSIDERATION OF PUBLIC COMMENT.—
7	The standard setting organization provides
8	for a process through which, after the pub-
9	lication of the notice referred to under
10	clause (i), the organization—
11	"(I) receives and responds to
12	public comments submitted on a time-
13	ly basis on the proposed addition or
14	modification before submitting such
15	proposed addition or modification to
16	the National Committee on Vital and
17	Health Statistics under clause (iii);
18	"(II) makes publicly available a
19	written explanation for its response in
20	the proposed addition or modification
21	to comments submitted on a timely
22	basis; and
23	"(III) makes public comments re-
24	ceived under clause (I) available, or

1	provides access to such comments, to
2	the Secretary.
3	"(iii) Submittal of final pro-
4	POSED ADDITION OR MODIFICATION TO
5	NCVHS.—After completion of the process
6	under clause (ii), the standard setting or-
7	ganization submits the proposed addition
8	or modification to the National Committee
9	on Vital and Health Statistics for review
10	and consideration under subparagraph (E).
11	Such submission shall include information
12	on the organization's compliance with the
13	notice and comment requirements (and re-
14	sponses to those comments) under clause
15	(ii).
16	"(E) Hearing and recommendations
17	BY NATIONAL COMMITTEE ON VITAL AND
18	HEALTH STATISTICS.—Under the upgrade pro-
19	gram, upon receipt of a proposal submitted by
20	a standard setting organization under subpara-
21	graph (D)(iii) for the adoption of an addition or
22	modification to a standard, the National Com-
23	mittee on Vital and Health Statistics shall pro-
24	vide notice to the public and a reasonable op-
25	portunity for public testimony at a hearing on

1	such addition or modification. The Secretary
2	may participate in such hearing in such capac-
3	ity (including presiding ex officio) as the Sec-
4	retary shall determine appropriate. Not later
5	than 90 days after the date of receipt of the
6	proposal, the Committee shall submit to the
7	Secretary its recommendation to adopt (or not
8	adopt) the proposed addition or modification.
9	"(F) Determination by secretary to
10	ACCEPT OR REJECT NATIONAL COMMITTEE ON
11	VITAL AND HEALTH STATISTICS RECOMMENDA-
12	TION.—
13	"(i) TIMELY DETERMINATION.—
14	Under the upgrade program, if the Na-
15	tional Committee on Vital and Health Sta-
16	tistics submits to the Secretary a rec-
17	ommendation under subparagraph (E) to
18	adopt a proposed addition or modification,
19	not later than 90 days after the date of re-
20	ceipt of such recommendation the Sec-
21	retary shall make a determination to ac-
22	cept or reject the recommendation and
23	shall publish notice of such determination
24	in the Federal Register not later than 30
25	days after the date of the determination.

1	"(ii) Contents of Notice.—If the
2	determination is to reject the recommenda-
3	tion, such notice shall include the reasons
4	for the rejection. If the determination is to
5	accept the recommendation, as part of
6	such notice the Secretary shall promulgate
7	the modified standard (including the ac-
8	cepted proposed addition or modification
9	accepted).
10	"(iii) Limitation on consider-
11	ATION.—The Secretary shall not consider a
12	proposal under this subparagraph unless
13	the Secretary determines that the require-
14	ments of subparagraph (D) (including pub-
15	lication of notice and opportunity for pub-
16	lic comment) have been met with respect to
17	the proposal.
18	"(G) Exemption from paperwork re-
19	DUCTION ACT.—Chapter 35 of title 44, United
20	States Code, shall not apply to a final rule pro-
21	mulgated under subparagraph (F).".
22	SEC. 202. UPGRADING ASC X12 AND NCPDP STANDARDS.
23	The Secretary of Health and Human Services shall
24	provide by notice published in the Federal Register for the

1	following replacements of standards to apply to trans-
2	actions occurring on or after April 1, 2009:
3	(1) Accredited standards committee X12
4	(ASC X12) STANDARD.—The replacement of the Ac-
5	credited Standards Committee X12 (ASC X12) ver-
6	sion 4010 adopted under section 1173(a) of such
7	Act (42 U.S.C. 1320d-2(a)) with the ASC X12 ver-
8	sion 5010, as reviewed by the National Committee
9	on Vital Health Statistics.
10	(2) National council for prescription
11	DRUG PROGRAMS (NCPDP) TELECOMMUNICATIONS
12	STANDARDS.—The replacement of the National
13	Council for Prescription Drug Programs (NCPDP)
14	Telecommunications Standards version 5.1 adopted
15	under section 1173(a) of such Act (42 U.S.C.
16	1320d-2(a)) with whichever is the latest version of
17	the NCPDP Telecommunications Standards that has
18	been approved by such Council and reviewed by the
19	National Committee on Vital Health Statistics as of

April 1, 2008.

1	TITLE III—PROMOTING THE USE
2	OF HEALTH INFORMATION
3	TECHNOLOGY TO BETTER CO-
4	ORDINATE HEALTH CARE
5	SEC. 301. SAFE HARBORS TO ANTIKICKBACK CIVIL PEN-
6	ALTIES AND CRIMINAL PENALTIES FOR PRO-
7	VISION OF HEALTH INFORMATION TECH-
8	NOLOGY AND TRAINING SERVICES.
9	(a) For Civil Penalties.—Section 1128A of the
10	Social Security Act (42 U.S.C. 1320a-7a) is amended—
11	(1) in subsection (a), by adding at the end the
12	following new sentence: "Paragraph (5) shall not
13	apply to nonmonetary remuneration (in the form of
14	health information technology or related installation,
15	maintenance, support, or training services) made by
16	a person to an individual described in such para-
17	graph if the provision of such remuneration is with-
18	out an agreement between the parties or legal condi-
19	tion that limits or restricts the use of the health in-
20	formation technology in conjunction with other
21	health information technology, if the person (or a
22	representative of such person) has not taken any ac-
23	tion to disable any basic feature of any hardware or
24	software component of such remuneration that

1	would permit interoperability, and if the remunera-
2	tion will assist with the individual's health care.";
3	(2) in subsection (b), by adding at the end the
4	following new paragraph:
5	"(4) For purposes of this subsection, induce-
6	ments to reduce or limit services described in para-
7	graph (1) shall not include the practical or other ad-
8	vantages resulting from health information tech-
9	nology or related installation, maintenance, support,
10	or training services."; and
11	(3) in subsection (i), by adding at the end the
12	following new paragraph:
13	"(8) The term 'health information technology'
14	means hardware, software, license, right, intellectual
15	property, equipment, or other information tech-
16	nology (including new versions, upgrades, and
17	connectivity) designed primarily for the electronic
18	creation, maintenance, or exchange of health infor-
19	mation to better coordinate care or improve health
20	care quality, efficiency, or research.".
21	(b) For Criminal Penalties.—Section
22	1128B(b)(3) of such Act (42 U.S.C. 1320a-7b(b)(3)) is
23	amended—
24	(1) in subparagraph (G), by striking "and" at
25	the end:

1	(2) in the subparagraph (H) added by section
2	237(d) of the Medicare Prescription Drug, Improve-
3	ment, and Modernization Act of 2003 (Public Law
4	108–173; 117 Stat. 2213)—
5	(A) by moving such subparagraph 2 ems to
6	the left; and
7	(B) by striking the period at the end and
8	inserting a semicolon;
9	(3) in the subparagraph (H) added by section
10	431(a) of such Act (117 Stat. 2287)—
11	(A) by redesignating such subparagraph as
12	subparagraph (I);
13	(B) by moving such subparagraph 2 ems
14	to the left; and
15	(C) by striking the period at the end and
16	inserting "; and; and
17	(4) by adding at the end the following new sub-
18	paragraph:
19	"(J) any nonmonetary remuneration (in
20	the form of health information technology, as
21	defined in section 1128A(i)(8), or related instal-
22	lation, maintenance, support or training serv-
23	ices) made to a person if—

1	"(i) the provision of such remunera-
2	tion is without an agreement between the
3	parties or legal condition that—
4	"(I) limits or restricts the use of
5	the health information technology to
6	services provided by the physician to
7	individuals receiving services at the
8	entity;
9	"(II) limits or restricts the use of
10	the health information technology in
11	conjunction with other health informa-
12	tion technology; or
13	"(III) conditions the provision of
14	such remuneration on the referral of
15	patients or business to the entity;
16	"(ii) such remuneration is arranged
17	for in a written agreement that is signed
18	by the parties involved (or their represent-
19	atives) and that specifies the remuneration
20	solicited or received (or offered or paid)
21	and states that the provision of such remu-
22	neration is made for the primary purpose
23	of better coordination of care or improve-
24	ment of health quality, efficiency, or re-
25	search; and

1	"(iii) the entity providing the remu-
2	neration (or a representative of such enti-
3	ty) has not taken any action to disable any
4	basic feature of any hardware or software
5	component of such remuneration that
6	would permit interoperability.".
7	(c) EFFECTIVE DATE AND EFFECT ON STATE
8	Laws.—
9	(1) Effective date.—The amendments made
10	by subsections (a) and (b) shall take effect on the
11	date that is 120 days after the date of the enact-
12	ment of this Act.
13	(2) Preemption of State Laws.—No State
14	(as defined in section 1101(a) of the Social Security
15	Act (42 U.S.C. 1301(a)) for purposes of title XI of
16	such Act) shall have in effect a State law that im-
17	poses a criminal or civil penalty for a transaction de-
18	scribed in the last sentence of section 1128A(a), sec-
19	tion $1128A(b)(4)$, or section $1128B(b)(3)(J)$ of such
20	Act, as added by subsections (a)(1), (a)(2), and (b),
21	respectively, if the conditions described in the re-
22	spective provision, with respect to such transaction,
23	are met.

1	SEC. 302. EXCEPTION TO LIMITATION ON CERTAIN PHYSI-
2	CIAN REFERRALS (UNDER STARK) FOR PRO-
3	VISION OF HEALTH INFORMATION TECH-
4	NOLOGY AND TRAINING SERVICES TO
5	HEALTH CARE PROFESSIONALS.
6	(a) In General.—Section 1877(b) of the Social Se-
7	curity Act (42 U.S.C. 1395nn(b)) is amended by adding
8	at the end the following new paragraph:
9	"(6) Information technology and train-
10	ING SERVICES.—
11	"(A) IN GENERAL.—Any nonmonetary re-
12	muneration (in the form of health information
13	technology or related installation, maintenance,
14	support or training services) made by an entity
15	to a physician if—
16	"(i) the provision of such remunera-
17	tion is without an agreement between the
18	parties or legal condition that—
19	"(I) limits or restricts the use of
20	the health information technology to
21	services provided by the physician to
22	individuals receiving services at the
23	entity;
24	"(Π) limits or restricts the use of
25	the health information technology in

1	conjunction with other health informa-
2	tion technology; or
3	"(III) conditions the provision of
4	such remuneration on the referral of
5	patients or business to the entity;
6	"(ii) such remuneration is arranged
7	for in a written agreement that is signed
8	by the parties involved (or their represent-
9	atives) and that specifies the remuneration
10	made and states that the provision of such
11	remuneration is made for the primary pur-
12	pose of better coordination of care or im-
13	provement of health quality, efficiency, or
14	research; and
15	"(iii) the entity (or a representative of
16	such entity) has not taken any action to
17	disable any basic feature of any hardware
18	or software component of such remunera-
19	tion that would permit interoperability.
20	"(B) Health information technology
21	DEFINED.—For purposes of subparagraph (A),
22	the term 'health information technology' means
23	hardware, software, license, right, intellectual
24	property, equipment, or other information tech-
25	nology (including new versions, upgrades, and

1	connectivity) designed primarily for the elec-
2	tronic creation, maintenance, or exchange of
3	health information to better coordinate care or
4	improve health care quality, efficiency, or re-
5	search.".
6	(b) EFFECTIVE DATE AND EFFECT ON STATE
7	Laws.—
8	(1) Effective date.—The amendment made
9	by subsection (a) shall take effect on the date that
10	is 120 days after the date of the enactment of this
11	Act.
12	(2) Preemption of State Laws.—No State
13	(as defined in section 1101(a) of the Social Security
14	Act (42 U.S.C. 1301(a)) for purposes of title XI of
15	such Act) shall have in effect a State law that im-
16	poses a criminal or civil penalty for a transaction de-
17	scribed in section 1877(b)(6) of such Act, as added
18	by subsection (a), if the conditions described in such
19	section, with respect to such transaction, are met.
	Amend the title so as to read: "A bill to promote a

Amend the title so as to read: "A bill to promote a better health information system."